Exhibit A

Comparison of Schedules 9 and 28 to Dr. Kessler's 09.26.2016 Report

Date	"Statement" from Schedule 28	Report Para.	Kessler Report 09.26.2016
2/13/2004	**REDACTED**	513.a.	**REDACTED**
4/15/2004	**REDACTED**	176	**REDACTED**

Date	"Statement" from Schedule 28	Report Para.	Kessler Report 09.26.2016
4/21/2004	Bard's April 21, 2004 Remedial Action Plan SPA 04-04-02 stated that "Vena Cava Filter Adverse Event frequency rates will be reviewed on a quarterly basis. Rates will be obtained from: Maude, IMS, Lexis/Nexis and other medical literature as identified during the search. A comparison of the Recovery Vena Cava Filter to all other Vena Cava Filters will be completed. Frequency rates will be compared to assure that adverse events associated with the Recovery Filter are not occurring with excess frequency. Although this report will be an important element in deciding product status, the Division PAT realizes that comparative attempts to assess similar events via the above mentioned information sources do not yield reliable quantitative estimates for the following reasons: 1. Potential under-reporting (Maude). 2. Potential over-reporter (IMS, sales data can only be roughly estimated). 3. Inadequate description of events in the Maude database, resulting in potential misclassification. 4. Very low frequency of events. 5. High variability in event rates and sales rates across devices and time periods."	499 n.80	Bard's R002 policy defined an "unacceptable" risk. Bard also utilized a criterion where it compared filters against other comparative filters. Bard's April 21, 2004 Remedial Action Plan SPA 04-04-02 stated that "Vena Cava Filter Adverse Event frequency rates will be reviewed on a quarterly basis. Rates will be obtained from: Maude, IMS, Lexis/Nexis and other medical literature as identified during the search. A comparison of the Recovery Vena Cava Filter to all other Vena Cava Filters will be completed. Frequency rates will be compared to assure that adverse events associated with the Recovery Filter are not occurring with excess frequency. Although this report will be an important element in deciding product status, the Division PAT realizes that comparative attempts to assess similar events via the above mentioned information sources do not yield reliable quantitative estimates for the following reasons: 1. Potential under-reporting (Maude). 2. Potential over-reporter (IMS, sales data can only be roughly estimated). 3. Inadequate description of events in the Maude database, resulting in potential misclassification. 4. Very low frequency of events. 5. High variability in event rates and sales rates across devices and time periods." (BPV-17-01-000153578) . . .
4/23/2004	"I believe that the under-reporting of non-significant migrations will be so extreme that calculating a 'proportion of migrations that are fatal' based on MAUDE data will be entirely suspect. We should stick to the much more likely to be reported event of filter associated death, compared to estimated sales. This also has the best clinical relevance for practitioners."	160	. . . I believe that the under-reporting of nonsignificant migrations will be so extreme that calculating a 'proportion of migrations that are fatal' based on MAUDE data will be entirely suspect. We should stick to the much more likely to be reported event of filter associated death, compared to estimated sales. This also has the best clinical relevance for practitioners. . .

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4/27/2004	In a Recovery Filter Migration HHE: "These types of adverse events occur with all known types of vena cava filters, and are extensively reported in the medical literature. Comparative attempts to assess similar events via the MAUDE database do not yield reliable quantitative estimates for a number of reasons: • Potential under-reporting • Inadequate description of events in the MAUDE database, resulting in potential misclassification • Very low frequency of observed events • Sales data can only be roughly estimated • High variability in event rates across devices and across time periods However, it is clear that since the MAUDE database has been kept, numerous instances of vena cava filters migrating to the heart with both fatal and nonfatal outcomes have been reported, as well as fatalities from the other known complications associated with the implantation of such devices."	166	Later in the Recovery Filter Migration HHE, Dr. Lehmann stated: . . . These types of adverse events occur with all known types of vena cava filters, and are extensively reported in the medical literature. Comparative attempts to assess similar events via the MAUDE database do not yield reliable quantitative estimates for a number of reasons: • Potential under-reporting • Inadequate description of events in the MAUDE database, resulting in potential misclassification • Very low frequency of observed events • Sales data can only be roughly estimated • High variability in event rates across devices and across time periods However, it is clear that since the MAUDE database has been kept, numerous instances of vena cava filters migrating to the heart with both fatal and nonfatal outcomes have been reported, as well as fatalities from the other known complications associated with the implantation of such devices."
4/21/2004	In the Bard Recovery Filter Migration Remedial Action Plan SPA-04-02, dated April 21, 2004, a tab titled "MAUDE Summary & Graphics," included the following tables shown in the paragraphs: This chart, titled "Migrations per Units Sold"	167-170	In the Bard Recovery Filter Migration Remedial Action Plan SPA-04-02, dated April 21, 2004, a tab titled "MAUDE Summary & Graphics," included the tables shown in the paragraphs infra. One chart titled "Migrations per Units Sold" revealed the following:

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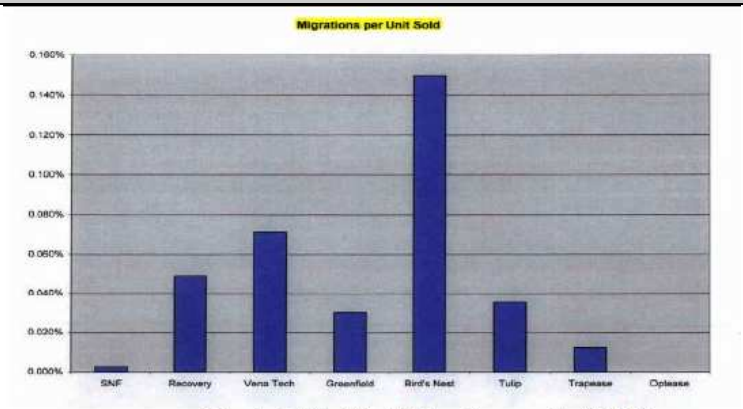
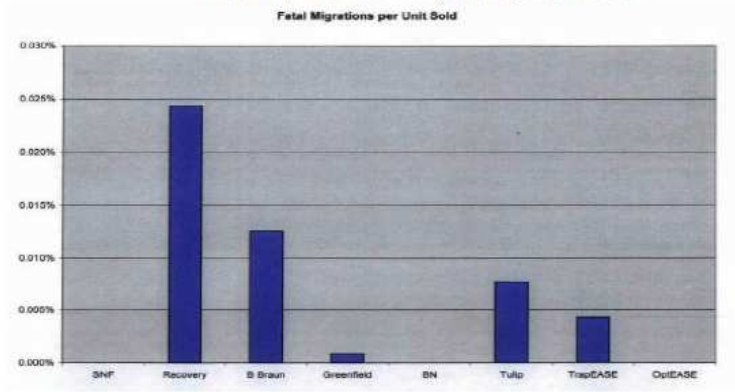
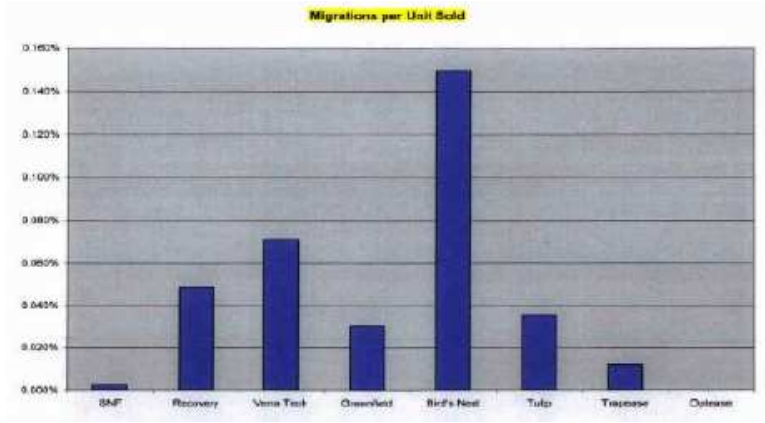
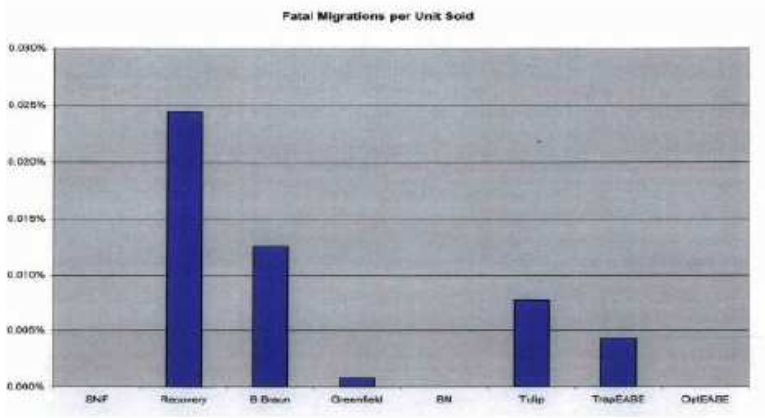
	 This chart, titled "Fatal Migrations per Unit Sold" 		 A chart titled "Fatal Migrations per Unit Sold" revealed the following: 

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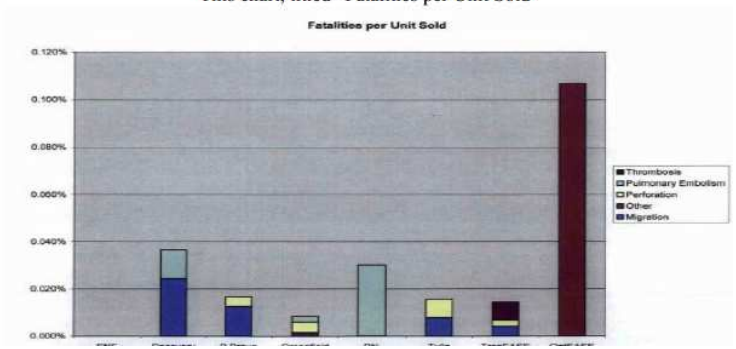
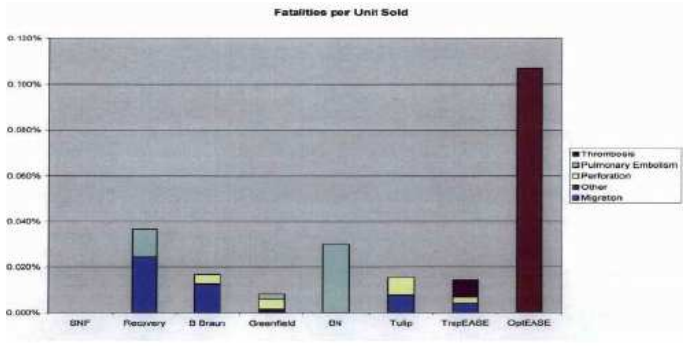
	This chart, titled "Fatalities per Unit Sold" 		Another chart titled "Fatalities Per Unit Sold" revealed the following: 
6/10/2004	**REDACTED**	209	**REDACTED**

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7/15/2004	Janet Hudnall circulated via email a corporate approved document titled "Vena Cava Filter Complications – FAQs," which included the following question and answer: "Q: Is Recovery® Filter a safe device? A: The Recovery filter was rigorously tested for all physical performance characteristics according to our established test methods and protocols and was found to meet all test specifications and requirements. As stated previously, Recovery® Filter's overall complication rates are comparable to those reported in the literature and the MAUDE database for other filters."	513.b	On July 15, 2004, Janet Hudnall circulated via email a corporate approved document titled "Vena Cava Filter Complications – FAQs," which included the following question and answer: "Q: Is Recovery® Filter a safe device? A: The Recovery filter was rigorously tested for all physical performance characteristics according to our established test methods and protocols and was found to meet all test specifications and requirements. As stated previously, Recovery® Filter's overall complication rates are comparable to those reported in the literature and the MAUDE database for other IVC filters." (BPVE-01-00268921-923 at 923)
11/17/2004	**REDACTED**	520	**REDACTED**
12/2004	**REDACTED**	180	**REDACTED**

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12/9/2004	**REDACTED**	217	**REDACTED**
12/9/2004	**REDACTED**	219	**REDACTED**
12/17/2004	Dr. David Ciavarella provided another Health Hazard Evaluation, with the subject line "Recovery Filter – Consultant's Report," on December 17, 2004, which noted, "Seventy-six reports of potentially serious hazards have been reported; 32 of those were judged to be serious, and 10 reports were associated with patient death.…An analysis of reporting rates of serious adverse events for all inferior vena cava filters, as determined by analysis of the MAUDE and IMS databases by a consultant, revealed that reporting rates for Recovery are significantly higher than other filters. However, these databases are subject to known, significant biases that make calculation or comparison of incidence rates among products unreliable and inadvisable (according to experts and the FDA)." Dr. Ciavarella concluded that "[t]he Frequency category for serious injury (Critical Severity rating) is Occasional (32/20,827, or 0.153%)."	221	Dr. David Ciavarella provided another Health Hazard Evaluation, with the subject line "Recovery Filter – Consultant's Report," on December 17, 2004, which noted, "Seventy-six reports of potentially serious hazards have been reported; 32 of those were judged to be serious, and 10 reports were associated with patient death.…An analysis of reporting rates of serious adverse events for all inferior vena cava filters, as determined by analysis of the MAUDE and IMS databases by a consultant, revealed that reporting rates for Recovery are significantly higher than other filters. However, these databases are subject to known, significant biases that make calculation or comparison of incidence rates among products unreliable and inadvisable (according to experts and the FDA)." Dr. Ciavarella concluded that "[t]he Frequency category for serious injury (Critical Severity rating) is Occasional (32/20,827, or 0.153%)." (BPVE-01-01019773-825 at 821)
12/17/2004	Dr. Ciavarella's report further stated, "Reports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4,	222	Dr. Ciavarella's report further stated, "Reports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4,

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	4.1, and 5.3 higher, respectively, than reporting rates for all filters. These differences were all statistically significant."		4.1, and 5.3 higher, respectively, than reporting rates for all filters. These differences were all statistically significant."
12/2004	In the December 2004 Health Hazard Evaluation, Dr. Ciavarella also noted the following: **Is the Problem Expected & Within an Acceptable Statistical Range**: From the analysis of the MAUDE and IMS databases, Recovery reporting rates are significantly higher than those of other filters. In conjunction with these data, there appears to be a significant correlation, although R2 values are only in the 0.5 range, of the migration reporting rates with the simulated migration resistance bench test. However, the flaws in the data collection methodologies makes calculation and comparison of actual incidence rates impossible from these data, and no definitive conclusions as to relative performance can be made. Adverse events rates reported in the literature are well above these reporting rates. But, as discussed above, direct comparisons of reporting rates to literature-derived rates are not possible because mostly permanent filters have been studied and the data have been collected using markedly different detection methods and patient populations. However, further investigation of these reported adverse events is warranted because of the size of the differences in the reporting rates and the correlation with the bench test of migration resistance."	223	In the December 2004 Health Hazard Evaluation, Dr. Ciavarella also noted the following: . . . "**Is the Problem Expected & Within an Acceptable Statistical Range**: From the analysis of the MAUDE and IMS databases, Recovery reporting rates are significantly higher than those of other filters. In conjunction with these data, there appears to be a significant correlation, although R2values are only in the 0.5 range, of the migration reporting rates with the simulated migration resistance bench test. However, the flaws in the data collection methodologies makes calculation and comparison of actual incidence rates impossible from these data, and no definitive conclusions as to relative performance can be made. Adverse events rates reported in the literature are well above these reporting rates. But, as discussed above, direct comparisons of reporting rates to literature-derived rates are not possible because mostly permanent filters have been studied and the data have been collected using markedly different detection methods and patient populations. However, further investigation of these reported adverse events is warranted because of the size of the differences in the reporting rates and the correlation with the bench test of migration resistance." . . .

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1/4/2005	**REDACTED**	224	**REDACTED**
1/4/2005	**REDACTED**	226	**REDACTED**
1/4/2005	**REDACTED**	228	**REDACTED**
1/4/2005	**REDACTED**	228	**REDACTED**
2/16/2005	**REDACTED**	236	**REDACTED**
4/19/2005	**REDACTED**	237	**REDACTED**

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7/16/2005	District Sales Manager Jason Greer emailed other Bard employees, including marketing executives Robert DeLeon and Janet Hudnall, regarding "Wesley's situation…everyone's situation," and stated, "Cordis has brought forward the Maude database to her physicians and caused a problem." Mr. Greer then suggested talking points during sales calls: "When you take out bariatric complications, our complications rates are lower than the other companies.…[M]ay I suggest the safest filter on the market that has been on the market for the longest time in its current form…The Simon Nitinol? If you want a filter that will give you the greatest chance of reducing your complications, The Simon Nitinol is that filter. (I have a spreadsheet from Maude that shows this)."	242	On July 16, 2005, District Sales Manager Jason Greer emailed other Bard employees, including marketing executives Robert DeLeon and Janet Hudnall, regarding "Wesley's situation…everyone's situation," and stated, "Cordis has brought forward the Maude database to her physicians and caused a problem." Mr. Greer then suggested talking points during sales calls: "When you take out bariatric complications, our complications rates are lower than the other companies.…[M]ay I suggest **the safest filter on the market that has been on the market for the longest time in its current form…The Simon Nitinol? If you want a filter that will give you the greatest chance of reducing your complications, The Simon Nitinol is that filter. (I have a spreadsheet from Maude that shows this)**." (BPV-DEP-00005665-666, Emphasis added)
7/18/2005	Janet Hudnall stated, "I handed out copies of the lists of accounts that were identified last Spring as 'special needs' accounts that could benefit from being included on the Roadshow.…" The "Comments" column included the following statements: • "Heard of [Redacted] migration and won't use" • "Recurrent PE resulting in death" • "Acc[ount] Has stopped using due to several reported complications" • "Stopped using; migration" • "Standard of care no longer Recovery; concerned about patient safety."	244	In the same email from July 18, 2005, Janet Hudnall stated, "I handed out copies of the lists of accounts that were identified last Spring as 'special needs' accounts that could benefit from being included on the Roadshow.…" . . . The "Comments" column included the following statements: • "Heard of [Redacted] migration and won't use" • "Recurrent PE resulting in death" • "Acc[ount] Has stopped using due to several reported complications" • "Stopped using; migration" • "Standard of care no longer Recovery; concerned about patient safety."

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	• "One of the first physicians to receive [Redacted] memo. Has not used it since." • "Had filter fracture and seen several arms outside the caval wall." • "Heard of [Redacted] migration and won't use" • "Confirmation that everything is good" • "Failed removal due to tilted filter in young patient" • "Recurrent PE resulting in death" • "Stopped using, migration" • "MAUDE concerns" • "The standard of care for San Diego is no longer Recovery. He does not want to put himself or his practice at risk." • "The entire group has stopped using Recovery. The trauma Drs. are concerned about the [Redacted] memo." • "Fracture Concerns"		• "One of the first physicians to receive [Redacted] memo. Has not used it since." • "Had filter fracture and seen several arms outside the caval wall." • "Heard of [Redacted] migration and won't use" • "Confirmation that everything is good" • "Failed removal due to tilted filter in young patient" • "Recurrent PE resulting in death" • "Stopped using, migration" • "MAUDE concerns" • "The standard of care for San Diego is no longer Recovery. He does not want to put himself or his practice at risk." • "The entire group has stopped using Recovery. The trauma Drs. are concerned about the [Redacted] memo." • "Fracture Concerns"
8/3/2005	**REDACTED**	246	**REDACTED**
11/7/2005	After being forwarded Brian Hudson's November 7, 2005 email regarding "G2 Perforations," Bard's Head of Quality Assurance emailed Gin Schulz, BPV V.P., QA, *et al.*, and stated, "Welcome to your first product challenge at BPV. It's obvious from the table below and the attached Maude summary that there are some major discrepancies regarding number of complaints, units sold, rates etc. for G2. Your first cut at a Maude Analysis sends some signals for Caval Perforation and deployment that have to be investigated expeditiously. We need to assess the complete field assurance summary for AE's on G2 and not look at the individual failures	389	After being forwarded Brian Hudson's November 7, 2005 email regarding "G2 Perforations," Bard's Head of Quality Assurance emailed Gin Schultz, BPV V.P., QA, *et al.*, and stated, "Welcome to your first product challenge at BPV. It's obvious from the table below and the attached Maude summary that there are some major discrepancies regarding number of complaints, units sold, rates etc. for G2. Your first cut at a Maude Analysis sends some signals for Caval Perforation and deployment that have to be investigated expeditiously. We need to assess the complete field assurance summary for AE's on G2 and not look at the individual failures and try to

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	and try to rationalize them away as not being significantly different. In an effort to avoid any confusion regarding field performance on G2 and the conclusions made over the root cause of the reported AE's, I want you and your team to do the following: - Conduct a comprehensive complaint investigation including trend analysis for G2 with factual, verifiable data for number of events, sales data, and rates. - Compare your findings to pre-established DFMEA/Risk analysis criteria and determine if the trends are still within anticipated occurrence rates. Also determine if the severity of these events is consistent with your original assessment. - Establish complaint thresholds for these events for future trending so we can determine if we are approaching alert and action limits. - Present your failure investigation findings for these AE's along with your proposals for short and long term corrective action. - Determine if your trends are significant enough to warrant the creation of a remedial action plan per Corp RA policy R-002.		rationalize them away as not being significantly different. In an effort to avoid any confusion regarding field performance on G2 and the conclusions made over the root cause of the reported AE's, I want you and your team to do the following: - Conduct a comprehensive complaint investigation including trend analysis for G2 with factual, verifiable data for number of events, sales data, and rates. - Compare your findings to pre-established DFMEA/Risk analysis criteria and determine if the trends are still within anticipated occurrence rates. Also determine if the severity of these events is consistent with your original assessment. - Establish complaint thresholds for these events for future trending so we can determine if we are approaching alert and action limits. - Present your failure investigation findings for these AE's along with your proposals for short and long term corrective action. - Determine if your trends are significant enough to warrant the creation of a remedial action plan per Corp RA policy R-002.
11/30/2005	**REDACTED**	391	**REDACTED**
8/1/2007	August 1, 2007 Report additionally stated, "Although most physicians believe that caudal migration has less serious patient safety implications than some other types of filter complications, they believe that a filter that moved caudally implies a general instability of the device	414	The same August 1, 2007 Report additionally stated, "Although most physicians believe that caudal migration has less serious patient safety implications than some other types of filter complications, they believe that a filter that moved caudally implies a general instability of

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	in situ and therefore felt less comfortable using it as their default filter….As well, a review of the MAUDE database was conducted, comparing the complaint rates of all commercially available filters against the SIR Guidelines."		the device in situ and therefore felt less comfortable using it as their default filter….As well, a review of the MAUDE database was conducted, comparing the complaint rates of all commercially available filters against the SIR Guidelines" (BPVE-01-00617777-793 at 783-784)
12/31/2007	**REDACTED**	449	**REDACTED**
2010	**REDACTED**	463	**REDACTED**

Date	"Important Quotes" from Schedule 9	Report Para.	Kessler Report 09.26.2016
3/10/2004	**REDACTED**	153	**REDACTED**
4/27/2004	**REDACTED**	165-166	**REDACTED**

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6/30/2004	"Of the 6 events involving thrombi-encased filters that migrated to the heart, 4 were associated with patient death." "The 'malfunction' is best understood as a limitation of the ability of the device to carry out its intended function." "The root cause of the migration event in these 10 cases is judged to be dislodgment of the filter due to the presence of a large thrombus. The exact mechanism of the dislodgment is unknown, but is presumed due to an acute increase in intracaval pressure (caudal to the filter) with resulting expansion of the IVC beyond the design limits of the filter." "There have been 10 cases of migration reported for the Recovery filter, and about 10,000 filters have been placed, giving a migration rate of approximately 0.1%." . . .	208	. . . An HHE by Dr. David Ciavarella dated June 30, 2004 stated, "Of the 6 events involving thrombi-encased filters that migrated to the heart, 4 were associated with patient death." The HHE indicated that one definition of migration involved whether the filter has moved as a component of a thromboembolus, where "the 'malfunction' is best understood as a limitation of the ability of the device to carry out its intended function." Dr. Ciavarella further reported that "The root cause of the migration event in these 10 cases is judged to be dislodgment of the filter due to the presence of a large thrombus. The exact mechanism of the dislodgment is unknown, but is presumed due to an acute increase in intracaval pressure (caudal to the filter) with resulting expansion of the IVC beyond the design limits of the filter." He further reported that "[t]here have been 10 cases of migration reported for the Recovery filter, and about 10,000 filters have been placed, giving a migration rate of approximately 0.1%." (BPVEFILTER-01-00014836-839)
7/9/2004	**REDACTED**	211	**REDACTED**
11/17/2004	**REDACTED**	216	**REDACTED**
12/17/2004	**REDACTED**	220-223	**REDACTED**

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2/15/2006	**REDACTED**	396-407	**REDACTED**